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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,838	04/20/2004	Stephanie M. Kladakis	022956-0261	5281
21125 7590 03/10/2010 NUTTER MCCLENNEN & FISH LLP SEAPORT WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
ART UNIT		PAPER NUMBER		
1647				
NOTIFICATION DATE		DELIVERY MODE		
03/10/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/828,838

Applicant(s)

KLADAKIS ET AL.

Examiner

CHERIE M. WOODWARD

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-14, 16-21, 23-27, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/26/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

1. Applicant's Response filed 1/26/2010 is acknowledged and entered. Claims 1-37 are pending. Claims 1-32 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 33-37 are under examination.

Information Disclosure Statements

2. The information disclosure statement (IDS) submitted on 1/26/2010 has been considered by the examiner to the extent possible. A signed copy is attached hereto.

References in non-English languages have not been considered and are lined through. To the extent that a non-English reference has an English-language abstract, only the English language abstract has been considered.

37 CFR 1.98(a)(2) requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. If the references have not been provided, they have not been fully considered.

Citations to search reports have been lined through. Search reports are only considered to the extent that each individual reference cited on the report is separately cited and provided for the examiner's consideration. In the instant case, the search reports are directed to other applications and not to the instant case. It is unclear whether the references contained in those search reports have been separately cited and provided to the examiner for review and consideration.

Applicant has also submitted a transmittal letter citing 14 "copending" applications, most with multiple Office Actions, without any statement as to the relevance, cumulative nature, or materiality of the references or any indication of the relevance or materiality of any prior art cited therein. Some of the "copending" applications have been allowed or abandoned as far back as 2004. It is also perplexing that the instant application was cited in the list as a "copending" application.

Additionally, there is no statement as to materiality or the cumulative nature of any of the references in the IDS document or list of "copending" applications. Applicant is reminded of the requirements of 37 CFR 1.56 and *Li Second Family Limited Partnership v. Toshiba Corp.*, 56 USPQ2d 1681 (Fed. Cir. 2000); accord *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.* 487 F.3d 897, 913. (Fed.Cir.2007). Applicants submissions have been made without any statement as to the

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relevance, cumulative nature, or materiality of the references or any indication of the relevance or materiality of any the art cited therein.

These references and copending applications have been considered to the extent possible given the issues set forth above, including Applicant's lack of compliance with 37 CFR 1.98, numerous foreign language documents, and the examiner's limited amount of time for examination.

Response to Arguments

Claim Rejections Maintained

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-8, 10-14, 16-21, 23-27, and 32-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman et al. U.S. Patent Publication US 20020127265 (12 September 2002) and

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Huckle et al., WO 01/85226 (published 15 November 2001), as evidenced by Boland et al., (J Macromol Sci –Pure Appl Chem. 2001;A38(12):1231-1243), for the reasons of record and the reasons set forth herein.

Applicant presents arguments that have previously been made of record and responded to. See prior Office Actions. Applicant argues that neither the '265 publication (Bowman) nor the '226 publication (Huckle) teach the required density of the nonwoven material, but rather Huckle only teaches the required density for the scaffold material, after a coating of PCL has been applied (Remarks, pp. 4-6). Applicant argues that the needled felt of Huckle does not have the required density and therefore Huckle fails to teach or suggest a nonwoven polymeric material having the recited density range (Remarks, p. 5). Applicant agrees that the claims do not prohibit that a coating on the dry-laid nonwoven polymeric material (Remarks, p. 5).

As previously explained of record, the crux of Applicant's argument is that the nonwoven material of the prior art contains a PCL coating which increases the density of the material, but that the material itself, without any coating, does not meet the requisite claim limitations regarding density. The examiner has explained that the examiner is required to read the claims in their broadest reasonable interpretation. The examiner has explained that the instant claims read on a method comprising a nonwoven polymeric material. The claims define that nonwoven polymeric material as having (read as "comprising") a density in the range of about 120 mg/cc to 360 mg/cc. The specification teaches several embodiments of nonwoven polymeric material including material comprising a PCL coating. Although limitations of the specification cannot be read into the claims, the claims are read in light of the specification, including the embodiments whereby the nonwoven polymeric material comprises a PCL coating, which is the same kind of coating taught by the prior art.

The examiner notes Applicant's argument that "[a]lthough the PCL coating allegedly increases the density of the composite scaffold, it does not change the density of the original non-woven material" (Remarks, p. 5) is the critical point of disagreement as to the interpretation of the claims and the applicability of the prior art to the claims, as written. Applicant is encouraged to review the specification for possible positive or negative limitations that may be used to amend the claim language to provide the distinction discussed by Applicant. As presently written, the claims use open transitional "comprising" language and the "non-woven material" comprising the PCL is subsumed within its scope, particularly in light of the embodiments taught in the specification.

Provisional Obviousness-Type Double Patenting Rejection

7. Claims 1, 7, 10-14, 19, and 24-27 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8-11 of copending Application No. 11/856,743, for the reasons of record. Applicant has stated that appropriate terminal disclaimers will be filed if warranted (Remarks, p. 6).
8. Claims 1, 7, 8, 19, 24-27, 32, and 33 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7-9, 12, and 13 of copending Application No. 11/856,741, for the reasons of record. Applicant has stated that appropriate terminal disclaimers will be filed if warranted (Remarks, p. 6).

Advisory Notice

9. Applicant should carefully review the file wrapper history of the case prior to responding. Applicant argues that a Terminal Disclaimer will be filed in copending 11/427,477 in page 6 of the Remarks. Applicant's attention is drawn to page 2 of the FAOM mailed 10/30/2009, wherein the Provisional ODP Rejection over the copending '477 application was withdrawn because the comparable claims in the '477 application that would be ODP over the instant claims, are withdrawn.

Conclusion

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647